



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/501,135

07/13/2004

Fabio Giannessi

725.1050

7877

20311 7590 04/01/2010
LUCAS & MERCANTI, LLP
475 PARK AVENUE SOUTH
15TH FLOOR
NEW YORK, NY 10016

EXAMINER

YOUNG, SHAWQUA

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

04/01/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

Office Action Summary	Application No. 10/501,135	Applicant(s) GIANNESI ET AL.	
	Examiner SHAWQUIA YOUNG	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7,9,10 and 12 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 1,3,7,9 and 10 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1, 3-5, 7, 9, 10 and 12 are currently pending in the instant application. Applicants have amended claims 1 and 12 in an amendment filed on February 12, 2010. Claims 1, 3, 7, 9 and 10 are rejected, claims 4 and 5 are objected and claim 12 is allowable in this Office Action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 12, 2010 has been entered.

I. *Response to Arguments/Remarks*

Applicants' amendment, filed on February 12, 2010, has overcome the rejection of claims 1, 3, 7, 9 and 10 under 35 USC 102(e) as being anticipated by Brooks, et al. (US 7,192,982); the rejection of claim 12 under 35 USC 112, second paragraph as being indefinite and the objection to claim 4 as being dependent upon a rejected based claim. The above rejections and objection have been withdrawn.

II. *Rejection(s)*

35 USC § 103 - OBVIOUSNESS REJECTION

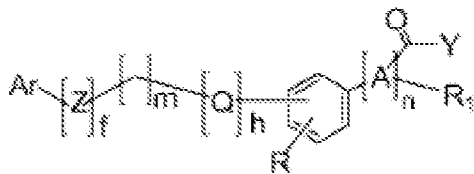
The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 7, 9 and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brooks, et al. (US 7,192,982). Applicants claim a compound of



formula

wherein A is CH, alkanylidene with 2

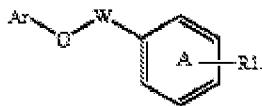
to 4 carbon atoms or alkenylidene with 2 to 4 carbon atoms; Ar is phenyl optionally substituted by halogens, C₁₋₄ alkyl, said alkyl substituted by at least one halogen; f is the

Art Unit: 1626

number 0 or 1; h is the number 0 or 1; m is a whole number from 0 to 3; n is the number 0 or 1 and if n is 0, R₁ is absent and COY is directly bound to benzene; Q is oxygen; Z is as defined in claim 1; R is selected from R₂ and OR₂; R₁ is as defined in claim 1; Y is selected from NH₂ and OR₅; R₅ is straight or branched C₁-C₄ alkyl and all other variables are as defined in claim 1.

The Scope and Content of the Prior Art (MPEP §2141.01)

Brooks, et al. teaches modulators of peroxisome proliferator activated receptors which are is represented by the general formula:



(V3)

The variables in Structural Formula (VI) are defined below.

Ar is a substituted or unsubstituted aromatic group. Preferably, Ar is an unsubstituted, monosubstituted or disubstituted aromatic group.

W is a substituted or unsubstituted alkylene linking group or a substituted or unsubstituted heteroalkylene linking group from two to ten atoms in length, preferably from two to seven atoms in length.

Phenyl Ring A is optionally substituted with up to four substituents in addition to R_1 .

R_1 is $-(CH_2)_n-CH(OR_2)-(CH_2)_m-COOR_3$, $-(CH)=C(OR_2)-(CH_2)_m-COOR_3$, $-(CH_2)_n-CH(Y)-COOR_3$ or $-(CH)=C(Y)-(CH_2)_m-COOR_3$. Preferably R_1 is meta or para to W and is represented by Structural Formula (II), more preferably by Structural Formula (III) and even more preferably by Structural Formula (IV). Structural Formulas (II)-(V) are shown above.

R_2 is $-H$, an aliphatic group, a substituted aliphatic group, an aryl group, a substituted aryl group, $-COR_4$, $-COOR_4$, $-CONR_5R_6$, $-C(S)R_4$, $-C(S)OR_4$ or $-C(S)NR_5R_6$.

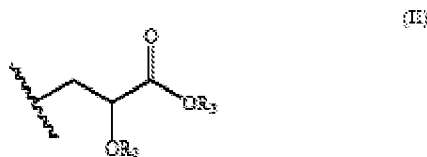
Y is $-O-$, $-CH_2-$, $-CH_2CH_2-$ or $-CH=CH-$ and is bonded to a carbon atom in Phenyl Ring A that is ortho to R_1 .

R_3-R_6 are independently $-H$, an aliphatic group, a substituted aliphatic group, an aryl group or a substituted aryl group.

n and m are independently 0, 1 or 2.

In Structural Formula (VI), preferably, R_2 is a C1-C6 lower alkyl group, phenyl, benzyl or benzoyl; and R_3 is $-H$ or a C1-C3 lower alkyl group.

See also the above preferred embodiments at columns 4-5, which disclose species teaching specific moieties. Note that at column 5, lines 15-16, variable R_1 is preferably meta or para to W and is represented by Structural Formula (II) which has



the following structure

(See column 4). The prior

art further teaches that in Structural (VI) R_2 is preferably a C1-C6 lower alkyl group, phenyl benzyl or benzoyl and R_3 is $-H$ or a C1-C3 lower alkyl (See column 5, lines 31-

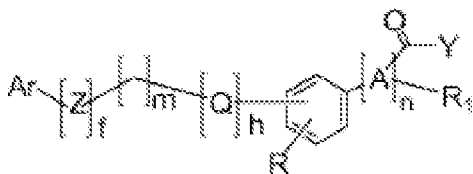
33). The prior art teaches various species such as (2S)-3-{4-[2-(3-fluoro-phenoxy)-ethoxy]-phenyl}-2-methoxy-propionic acid (See ex. 322, column 320) wherein R₃ is –H.

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Brooks, et al.* and the instant invention is that there is homologous subject matter. Not all of the substituents are taught, however there is overlap between the substituents disclosed especially in view of the preferred embodiments taught by the prior art. The instant compounds contain a carbonyl group wherein Y can be OR₅ and R₅ is a straight or branched C₁-C₄ alkyl whereas the prior art teaches a species wherein R₃ (equivalent to Applicants' variable Y) is H but teaches in preferred embodiments that the variable R₃ is preferably H or a C₁-C₃ lower alkyl group.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

Applicants are claiming a compound of the formula



wherein specifically Y is OR₅ and R₅ is a straight or branched C₁-C₄ alkyl. The prior art reference of *Brooks, et al.* teaches a similar compound wherein the substituents of R₃ (equivalent to the Y in the instant application) is preferably –H or C₁-C₃ alkyl (See column 5, lines 31-33). The prior art reference also teaches the specific compound (2S)-3-{4-[2-(3-fluoro-phenoxy)-ethoxy]-phenyl}-2-methoxy-propionic acid.

In In re Boe, 355 F.2d 961, 148 USPQ 507 (CCPA 1966), it was well established

Art Unit: 1626

that a reference is not limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. For example, it is obvious to prepare a -C(O)-O-C₁-C₄ alkyl group (See Applicants' -C(O)Y group) when the prior art teaches a species that contains a -COOH group but the preferred embodiments of the prior art reference teaches that the group could also be a -C(O)-O-C₁-C₃ alkyl with a reasonable expectation of success. Specifically, the prior art teaches preferred embodiments which embrace compounds that contain a -C(O)-O-C₁-C₃ alkyl group as seen in the instant claims. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to modify the -COOH group of the species 2S)-3-{4-[2-(3-fluoro-phenoxy)-ethoxy]-phenyl}-2-methoxy-propionic acid to a -C(O)-O-C₁-C₃ alkyl group based on the teachings of the preferred embodiments in the prior art (See column 5, lines 31-33). The motivation for one of ordinary skill in the art to make the above modification would be to prepare more PPAR modulators for the treatment of various diseases, such as type II diabetes. A strong prima facie obviousness has been established.

III. **Objections**

Claim Objections

Claim 5 is objected to because of the following informalities: for the misspelled term “proenoate” in the compound (Z)-2-ethoxy-3-[4-[2-(4-chlorophenyl)ethoxy]-phenyl]ethylproenoate (page 4, line 7). The term should read “propenoate”. Correction

Art Unit: 1626

is required.

Dependent Claim 4 is objected to as being dependent upon a rejected based claim.

IV. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

Application/Control Number: 10/501,135
Art Unit: 1626

Page 9